

AUG 20 1996

K962838

510(k) SUMMARY

July 20, 1996

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

1. Submitter:  
CeraMed Corporation  
12860 West Cedar Drive  
Lakewood, CO 80228  
(303) 985-0800
2. Device Name:  
PermaRidge syringe  
Classification Name: Syringe for Restorative and Impression Material
3. Predicate Device:  
OsteoGraf glass syringe  
Bio-Interfaces syringe
4. Device Description:  
The PermaRidge syringe is a device used for the delivery of restorative and impression material. It is composed of a plastic barrel, polypropylene plunger, and rubber plunger tip.
5. Intended Use:  
Delivery of restorative and impression material.
6. Comparison of Product Characteristics:  
The PermaRidge syringe consists of a plastic (cellulose acetate propionate) barrel, polypropylene plunger, and rubber plunger tip.